PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 101161-1 WO	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/SE2004/001113	International filing date (*day/month/year*) 08 July 2004 (08.07.2004)	Priority date (*day/month/year*) 11 July 2003 (11.07.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ASTRAZENECA AB		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 16 January 2006 (16.01.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Philippe Becamel
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Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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Global Intellectual Property
SE-151 85 Södertälje

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	11-11-2004
Applicant's or agent's file reference	**FOR FURTHER ACTION** See paragraph 2 below
101161-1 WO	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/SE2004/001113	08.07.2004	11.07.2003

International Patent Classification (IPC) or both national classification and IPC
A61K 47/36, A61K 47/34, A61K 9/08, A61K 9/14

Applicant
AstraZeneca AB et al

1. This opinion contains indications relating to the following items:
   - ☒ Box No. I Basis of the opinion
   - ☐ Box No. II Priority
   - ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

   If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

   If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

   For further opinions, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/SE2004/001113

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language, _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/SE2004/001113

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1-15

because:

☒ the said international application, or the said claims Nos. 1-15 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

See PCT Rule 67.1.(iv).: Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ The claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in the Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/SE2004/001113

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims		YES
	Claims	16-20	NO
Inventive step (IS)	Claims		YES
	Claims	16-20	NO
Industrial applicability (IA)	Claims	16-20	YES
	Claims		NO

2. Citations and explanations:

The following documents are cited in the International Search Report:

D1 WO 94/25070 A1
D2 WO 88/06893 A1
D3 WO 00/06122 A1
D4 WO 95/34292 A2
D5 WO 03/009846 A1
D6 WO 98/24414 A1
D7 US 5817338 A1

The claimed invention relates to a method for oral administration of acid labile proton pump inhibitor compounds. The problem to solve is the treatment of patients with difficulties in swallowing and for pediatric patients. This is solved by mixing the coated compounds with one or more pharmaceutically acceptable thickeners and an aqueous carrier. The thickener is capable of forming a viscous medium when dispersed in the aqueous medium. The formed aqueous suspension is administrated through a gastric tube or syringe.

D1 discloses a pharmaceutical composition for oral administration comprising a coated proton pump inhibitor, incorporated into a paste-like gel. This is obtained by mixing a coated proton pump inhibitor with dry gelling agent(s)before adding water. The composition is mixed in a syringe.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V

The claimed oral composition and the known composition contain the same ingredients and are obtained in the same way. Thus, claims 16-20 lack novelty.

The information, that the known composition is aimed at animals, lacks meaning in this connection.

D2 discloses an oral composition which is adapted to be dispersed in an aqueous carrier which comprises a multiplicity of particles comprising an active substance, said particles being combined with one or more gelling or swelling agents capable of forming a viscous medium around the particles in an aqueous carrier.
In example 1, a pre-mixed gel was prepared from water and Veegum(R) PRO. The coated crystals are mixed with the pre-mixed gel. This formulation made the crystals easy to swallow.

The claimed invention differs from D2 in that the mentioned active agents are not the same.

D3 (claim 20) discloses a method of producing a pharmaceutical composition, which comprises (1) preparing a drug-containing substance (2) preparing a gelling agent capable of gelling at normal temperature when added to water, and (3) mixing the drug-containing substance and the gelling agent.

D4 discloses in example 10 enteric-coated Lactobacillus acidophilus microgranules in yoghurt.

D5 discloses different examples of formulations containing a swelling/thickener agent and water.

D6 discloses a pharmaceutically acceptable liquid excipient suspending base for pharmaceutically active compounds, which liquid excipient suspending base comprises water, xanthan gum and hydroxypropyl methylcellulose.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V

D7 discloses multiple unit tableted dosage form of omeprazole.

A solid composition according to claims 16-18, the use of a thickener according to claim 19 and the use of a viscous medium according to claim 20 are not considered to involve an inventive step (Article 33(3) PCT). There are several compositions known in the art which, by a person skilled in the art, can easily be adapted to the claimed solid composition and the use of thickeners. D2-D6 comprise active agents similar to those of the present invention mixed in compositions similar to those of the examples in the present application. Considering what is known from D1 and other prior art it is considered to lie within the skills of a person skilled in the art, to prepare a solid composition comprising a proton pump inhibitor in a form of coated pellets (from D7), wherein the pellets are in admixture with one or more thickeners capable of forming a viscous medium when dispersed in an aqueous carrier.

Thus, claims 16-20 lack novelty and inventive step.